

Legal Framework for Implementation of Trans-fat Regulations in India

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Abstract

Background: The widespread consumption of trans-fats across the world represents a worrying scenario, as it is directly responsible for coronary heart disease and related mortality. Recognizing its dangers, the WHO has set an agenda to eliminate trans-fats by 2023. In India, the Food Safety And Standards Authority ensures safe and wholesome food consumption. In light of the WHO's standards for the elimination of trans-fats, the FSSAI recently notified limits of trans-fatty acids to not more than 3% in all fats and oils by January 2021 and 2% by January 2022, as well as a limitation on all food products in which edible oils and fats are ingredients to not contain trans-fatty acids of more than 2% mass of total oils/fats in the product by January 2022.

Objective: Given the need to eliminate the consumption of trans-fats, it is necessary to assess the implementation of trans-fat regulations in India in order to determine the current status of enforcement and suggest measures for improvement.

Methods: Empirical research was conducted through a questionnaire to analyze India's current status and difficulties in enforcing trans-fat regulations.

Results: Although all states have included compliance of trans-fat regulation in the agenda of the State Surveillance Plan but are facing some implementation challenges such as lack of lab infrastructure, lack of trained manpower, unsupportive FBOs, insufficient budget, lack of testing kits, and excluding proprietary food from compliance with trans-fat regulations. Further, all states have felt the need to develop a guideline/manual to facilitate enforcement of the trans-fat regulations.

In light of this, the article has critically analyzed the legal framework for implementing trans-fat regulations in India to identify specific implementation challenges due to scattered regulations and recommend suggestive measures for developing the guidelines/manual to facilitate effective implementation of the said regulation.

Keywords: Trans fatty acids, Oils, Coronary disease, Surveys and questionnaires, Workforce, World health organization.

INTRODUCTION

Trans fatty acids (TFAs) are primarily produced industrially through the process of partial hydrogenation of vegetable oils, which creates a semi-solid fat – partially hydrogenated oils (PHOs) – including Vanaspati, margarine, and bakery shortening. PHOs are less expensive, enhance taste, prolong product shelf life, and are commonly found in baked and fried foods, vegetable shortenings, blended ghee, cooking oils, and spreads. Vanaspati is used in India to prepare fried snacks, baked goods, and food preparation by restaurants and street food vendors. Existing data on the consumption of trans-

fats worldwide suggests that the daily average consumption of adults aged over 20 years in South-East Asian countries comprises nearly 0.5 to 1.24% of energy/day.

The consumption of TFAs poses a serious threat to human health. There is conclusive evidence that its consumption is strongly associated with an increased risk of coronary heart disease and related mortality, especially if trans-fats provide

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more than 1% of the energy/day. As per studies, nearly 63,243 deaths due to coronary heart disease in 2010 in India were attributable to high TFA intake. Removal of TFAs from food supply is considered an important means of public health policy for improving citizens' health status and tackling the problem of diet-related non-communicable diseases in low and middle-income countries.

Considering these adverse effects, the World Health Organisation (WHO) has made the elimination of industrially-produced TFAs a global priority, and countries around the world have taken action to protect their populations from TFA consumption. The WHO recommends: (i) limiting TFA to 2 g/100 g total fat in all fats, oils, and foods; or (ii) banning the production and use of PHOs as legal or regulatory measures to protect public health from TFA. The WHO launched the REPLACE action package, which seeks to eliminate industrially-produced trans-fat from nations with the goal of global elimination by 2023. It contains an overarching technical manual that provides a rationale and framework for an integrated approach to eliminate trans-fat. It includes six modules – review, promote, legislate, assess, create, enforce and additional online resources.

Considering the standards set by WHO, the Food Safety and Standards Authority of India (FSSAI) took two important steps:

- In December 2020, FSSAI gazetted the regulation, Food Safety and Standards (Food Products Standards and Food Additives) Tenth Amendment Regulations, 2020¹ to limit industrial TFA (trans-fatty acids) to not more than 3% in all fats and oils by January 2021 and not more than 2% by January 2022.
- The FSSAI gazetted the Food Safety and Standards (Prohibition and Restrictions on Sales) Second Amendment Regulations, 2021 to limit the TFA fat content in all food items. According to the regulation, all food products in which edible oils and fats are used as an ingredient shall not contain industrial trans fatty acids more than 2% by mass of the total oils/fats present in the product, on and from 1st January 2022.²

This article seeks to understand the success of these measures in reducing the consumption of trans-fats in India. Accordingly, it is divided into three broad parts – the first part examines the legal framework for the regulation of trans-fats in India. The second part discusses the results of a survey undertaken to analyze the implementation of trans-fats regulations in India. Finally, the third part concludes with suggestions to improve the legal framework for better implementation.

Legal Framework for Regulation of Trans-Fats in India

The underlying principle for regulating and eventually ending trans-fats consumption is based on the right to life enshrined under Article 21 Constitution of India.

Article 21 of the Constitution may be interpreted to include

right to live with human dignity, which may include the right to food and other basic necessities. As held by the Hon'ble Supreme Court in *Centre for Public Interest Litigation v. Union of India and ORS.*, the right to food means and includes right to safe food, observing that any food article which is hazardous or injurious to public health has a potential danger to life and violates the fundamental right to life guaranteed under Article 21. Further, it is the duty of the state to raise the level of nutrition and the standard of living and to improve public health guaranteed under Article 47 of Indian Constitution.

Thus, the citizens' constitutional right is being violated through trans-fat content food. To fulfil its constitutional duties, special legislations such as National Food Security Act, 2013 and Food Safety and Standards Act, 2006 have empowered the FSSAI to monitor the manufacturing, processing, distribution, sale and import of food to ensure safe and wholesome food and to frame regulations.

National Policy for Regulation of Trans-Fat in India and FSSAI

The FSSAI in pursuance of its power, to regulate transfat enacted the following regulations;

- Food Safety and Standards (Food Products and Food Additives) Regulations 2011 Trans-fat limits are established in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 which forms basic trans-fat regulation. The amount of permissible trans-fats in food has steadily reduced as the years progressed i.e. in 2013, to not more than 10% by weight, in food items such as interesterified vegetable fat, margarine and fat spreads, hydrogenated vegetable oils was introduced. In 2015 a limit of TFAs reduced to 05% and in 2020 reduced to 03%. Further, the limit was reduced to not more than 2% by weight, effective from 1st January 2022.
- Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations 2011. The regulations states that food products in which edible oils and fats are used as an ingredient shall not contain industrial trans-fatty acids more than 2% by mass of the total oils/fats present in the product.
- Food Safety and Standards (Labelling and Display) Regulations 2020. The Regulations provide for mandatory disclosure of certain information about the product on the product's label to help consumers make informed choices. These regulations have been amended to provide for the display of trans-fat (other than naturally occurring trans-fat) on the label of the product. The regulations state that nutritional information per 100g or 100 mL or per single consumption pack of the product and per serve percentage (%) contribution to recommended dietary allowance calculated on the basis of 2000 kcal energy, 67 g total fat, 22 g saturated fat, 2 g trans-fat, the requirement for an average adult per day, shall be

given on the label containing the amount of, total fat (g), saturated fat (g) and trans-fat (other than naturally occurring trans-fats)(g). Further, the regulations state that every package of edible oil, inter-esterified vegetable fat, both hydrogenated or partially hydrogenated oils, edible fats, margarine and fat spreads (mixed fat spreads and vegetable fat spread) and the package of food in which fat, oils and fat emulsion are used as ingredients shall declare the quantity of trans fat content and saturated fat content on the label.

- Food Safety and Standards (Advertising and Claims) Regulations 2018. This regulation, derives that the Nutrition claim of the food should adhere to the conditions laid down under Schedule I Entry 6 of these regulations that to held a food item “trans-fat free” that food items should contain less than 0.2 gram of trans fat per 100 g or 100 mL of food.

Food Safety and Standards (Safe Food and Balanced Diets for Children in School) Regulations 2020. This regulation impose certain responsibilities on the school authorities and individuals to protect the children from food containing high trans-fat levels. As per these regulations, the school authorities shall ensure that no person shall sell or offer for sale including the free sale, or permit the sale, of food products high in saturated fat or trans-fat or added sugar or sodium in school premises or campus. All the school authorities shall ensure that the board contains the warning “Do not sell including free sale or market or advertise the food products high in saturated fat or trans-fat or added sugar or sodium within school premises or campus” in English or one Indian language as applicable, is displayed prominently at the entrance gate or gates of the school. The School Authorities shall prohibit any advertisement banner or wallpaper of food that is high in saturated fat or trans-fat or added sugar or sodium on school computers. Also, no person shall advertise or market or sell or offer for sale, including the free sale, or permit sale of, food products high in saturated fat or trans-fat or added sugar or sodium in the school campuses or to school children in an area within fifty meters from the school gate in any direction.

Status of Enforcement of Trans-Fat Regulations in India

Given the immediate need to stop the consumption of trans-fats, it is necessary to determine the enforcement of trans-fat regulations in India. On the basis of such determination, proper measures must be taken to develop a more cohesive and rigorous framework for trans-fat regulation. Accordingly, this part discusses the survey undertaken to determine about the status of enforcement of trans-fat regulations in India.

NLSIU conducted a survey with the support of local partners in the states of Karnataka, Bihar, Jharkhand, Kerala, Punjab, Rajasthan, and Tamil Nadu between March 2021 to July 2021. Various legislations, including Food Safety and Standards Act 2006. The Food Safety and Standards (Food Products

Standards and Food Additives) Regulations, 2011, The Food Safety and Standards (Prohibition and Restrictions on Sales) second amendment Regulations, 2021, Food Safety and Standards (Labelling and Display) Regulations, 2020, Food Safety and Standards (Packaging and Labelling) Regulations, 2011 were looked into while formulating the questionnaire.

The questions were framed to analyse the status of enforcement of trans-fat regulations in India. The questionnaire were shared with Food Authority of 15 states, including Jharkhand, Bihar, Kerala, Punjab, Tamil Nadu, Karnataka, Gujarat, Goa, Assam, Haryana and Rajasthan. Seven states responded to the questionnaire, which has been recorded while framing the report.

Key Findings of the Survey

The key findings of the surveys were as follows:

- States that participated in the survey were aware of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2020, which mandate the maximum limit of trans-fatty acid to be not more than 3% by weight, on and from 1st April 2021 in oils and fats and 2% from 1st January, 2022.
- States that have collected the samples from the food business operators in their jurisdiction through surveillance/statutory methods and tested the trans-fat levels in various food items.
- States used AOAC 996.06 method for analysis of trans-fat and standards of 37 fame mix is being used by them for testing. However, none of the states reported any strict actions for violation of trans-fat regulations.
- State food departments are facing some implementation challenges such as lack of lab infrastructure, lack of trained manpower, unsupportive FBOs, insufficient budget, lack of testing kits, and excluding proprietary food from compliance with trans-fat regulations.
- All States have included compliance of trans-fat regulation in the agenda of the state surveillance plan prepared by the State Food Authority every year.
- All states felt the need for developing a guideline/manual to facilitate enforcement of the trans-fat regulations.

DISCUSSION

- The industrial produced trans fats and its consumption is proven to be causative of cardiovascular disease and it stands at the top priority to battle against it. The WHO is steering the momentum at the global level to eliminate trans-fat with its replace action package aiming for elimination by 2023. The countries like Chile, Denmark, Ecuador, Iceland, Norway, Singapore, and South Africa limits trans fat to 2% in all foods. Austria, Latvia, and Hungary limits trans fat to 2% in all foods subject to some exceptions; Armenia, Belarus, Russian Federation, and Switzerland Limits trans fat to 2% in fats, vegetable oils and margarine; Argentina, Colombia, and Saudi Arabia limits trans fat to 2% in fats, vegetable oils, and

margarine and trans fat to 5% in all food products and finally countries like Canada and United States limits on partially hydrogenated Oil.

- India's endeavor to regulate trans-fats through Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2021 limit the TFA fat content in all food items, including packaged food products, unorganized sector, street food vendors and kiosks. According to the regulation, all food products in which edible oils and fats are used as an ingredient shall not contain industrial trans fatty acids more than 2% by mass of the total oils/fats present in the product, on and from 1st January 2022 but the implementation of the regulation is the challenge in India. Specifically, the challenges like procedure for the collection of samples; Testing of samples; Non-accreditation of laboratories; Inadequate Enforcement Agencies/personnel; prolonged procedures; scattered rules and regulations and so on, has hindered the effective implementation of this regulation due to lack of a framework to guide the regulators/food safety officers.

CONCLUSION AND SUGGESTIONS

The efforts and ambitions of FSSAI are commendable in designing policies towards the safety of consumers. However, a framework is lacking to guide state-level food regulators/food safety officers to enforce the regulations on trans-fat levels in oils and fats. The framework, once developed, could ensure the effective implementation of FSSAI's TFA regulations. While FSSAI is the nodal agency at the national level, no regulations can succeed without individual states' and cities' active involvement and dedicated efforts. The PHO industries are based in multiple states and the responsibility of overseeing regulatory compliance through collection and testing of samples comes down to the state governments. The MoH and the FSSAI need to focus on the policy's ground-level implementation through mapping the trans-fat's current status, stakeholder engagement, capacity building, and enforcement.

Suggestions

Based on the study of regulations and survey conducted, the following suggestions are proposed:

Mapping of the existing state-wise status

- Mapping of PHVO Manufacturing units within state needs to be conducted for developing a baseline of how many industries are active as on date
- The usage pattern of partially hydrogenated oils (Vanaspati), fats, and oils at the industrial and household levels needs to be understood. PHVOs are commonly used in institutional and household cooking. In India, usage varies geographically, and a baseline idea of the usage sets the tone.
- Testing of TFA levels in fats and oils, including PHO, must be conducted in NABL accredited labs with certain parameters. Operational knowledge of labs will help in implementation and testing.

- Key stakeholders shall be mapped to identify and create a circle of influence. Enforcing trans-fat regulation at the state level is a complex phenomenon involving multi-stakeholder management. Some of the crucial stakeholders are the Ministry of Health, Food and Drug Administration, Confederation of Indian Industry, Food manufacturer association, oil manufacturer association.

Engagement with stakeholders

Developing a potential stakeholder advocacy and engagement plan is another important step that shall be done by involving all possible stakeholders such as:-

- FDA- Commissioner, Food and Drug Administration;
- MoH- Principal Secretary, MD-NHM, Directorate of Health Services; State NCD Nodal Officer;
- CII-Confederation of Indian Industries, State Chapter (Oil Producers Association);
- Food Industry Association- Formal and Informal (If Any);
- Cardiovascular Society, Indian Medical Association;
- Education Officer;
- Medical colleges of Repute,
- District level Engagements: Engagement of District Collector for achieving optimum impact who can be the nodal person between Food Safety Officers, NCD Nodal Officers, and Industry;

The industry engagement should be cautiously undertaken to prevent potential conflicts of interest.

Capacity Building

Capacity-building activities for enforcement shall be carried out which shall include modular cascade training of state and district-level food safety officers from the Food safety department, training of all lab personnel for effective functioning of state and district lab network, and training of food manufacturers on the usage of a healthy alternative to Hydrogenated vegetable oils.

Enforcement

- According to the provisions of FSSA, enforcement shall be done by strengthening the multi-stakeholder state-level and district level task force committee which should consist of members from the department of agriculture, commerce, food processing, industries, consumer affairs, research organizations and civil society organizations.
- Designated Food Safety Officers shall collect samples at retail and factory levels.
- Surveillance testing of fats and oils with TFA, including PHO at NABL-accredited labs shall be conducted.
- Verification of labels of trans-fat content declared by the manufacturer and report received from NABL testing labs shall be done.
- Any mismatch can be verified by statutory testing of fats and oils with TFA, including PHO, at NABL-accredited labs under close observation of the food safety department.
- If there are mismatches, manufacturers of fats and oils with TFA, including PHO, can be issued a written

warning and/or fined under sections of the Food Safety Act. Designated Food Safety Officers have the ability to issue fines under the Food Safety Act.

Quarterly Submission Report to FSSAI

- A quarterly report shall be submitted to FSSAI about the enforcement activities carried out.
- A quarterly Report of fats and oils testing with TFA, including PHO, as required by FSSAI shall be developed.
- Quarterly meetings at the state level for each district shall be organized to review the testing and action taken report by offices of each district.

REFERENCES

1. 'Trans Fatty Acids and Hydrogenated Vegetable Oils' <https://www.fsai.ie/faq/trans_fatty_acids.html> accessed 20 February 2022
2. Renata Micha et al, 'Global, regional, and national consumption levels of dietary fats and oils in 1990 and 2010: a systematic analysis including 266 country-specific nutrition surveys' (2014) *BMJ* <<https://www.bmj.com/content/348/bmj.g2272>> accessed 20 February 2022
3. Dariush Mozaffarian et al, 'Trans fatty acids and cardiovascular disease' (2006) 354 *NEJM* 1601
4. Qianyi Wang et al, 'Impact of Nonoptimal Intakes of Saturated, Polyunsaturated, and Trans-fat on Global Burdens of Coronary Heart Disease' (2016) 5(1) *Journal of American Heart Association* <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4859401/>> accessed 20 February 2022
5. World Economic Forum & WHO, *From Burden to "Best Buys": Reducing the Economic Impact of Non-Communicable Diseases in Low- and Middle-Income Countries* (2011)
6. REPLACE is an action package to eliminate industrially-produced trans-fat from the global food supply <<https://www.who.int/teams/nutrition-and-food-safety/replace-trans-fat#:~:text=The%20REPLACE%20action%20package%20provides,heart%20disease%20mortality%20and%20events.>>> accessed 20 February 2022
7. *In Re: Problems And Miseries of Migrant Labourers* Suo motu Writ Petition (Civil) No.6/2020
8. *Centre for Public Interest Litigation v. Union of India and Ors*, Writ petition (Civil) No. 681/2004
9. Food Safety and Standards Act 2006, s 16.
10. Food Safety and Standards Act 2006, s 92.
11. FSSAI Notification No. F. No. P. 15014/1/2011-PFA/FSSAI dated 27th June 2013
12. FSSAI Notification No. F. No. 4/15015/30/2011-PFA/FSSAI dated 4th August 2015
13. FSSAI Notification No. F. No. 1-116/Scientific Committee/Notif./2010-FSSAI dated 29th December 2020 w.e.f. 1st January 2021
14. FSSAI Notification No. F. No. 1-116/Scientific Committee/Notif./2010-FSSAI dated 29th December 2020 w.e.f. 1st January 2022
15. FSSAI Notification No. F. No. 1-116/Scientific Committee/Notif./2010-FSSAI dated 2nd February 2021 w.e.f. 01st January, 2022
16. FSSAI Notification No. F. No. 1-94/FSSAI/SP(Labelling)/2014(Pt-2) dated 17th November 2020 w.e.f. 17th November 2022
17. FSSAI Notification No F. No. 1-94/FSSAI/SP(Claims and Advertisements)/2017 dated 19th November 2018 w.e.f. 1st July 2019
18. FSSAI Notification No F. No. 15(1)2016/School Children Regulation/Enf/FSSAI dated 4th September 2020 w.e.f. 1st July 2021
19. Chopra S, Arora C, Malhotra A, Khurana SC., Industrially produced trans-fat: Usage, health implications, Global and Indian Regulations. *Indian J Public Health* 2021;65:71-5.